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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/828, 143	03/24/97	HSIA	H 24400-101

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HM12/0305 EXAMINER
MARX, I

ART UNIT	PAPER NUMBER
1651	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/828,143	Applicant(s) Hsia
	Examiner Irene Marx	Group Art Unit 1651

Responsive to communication(s) filed on Jan 19, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 9-15 is/are pending in the application.

Of the above, claim(s) 9-11 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 12-15 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The amendment filed 1/19/99 is acknowledged. Claims 12-15 are being considered on the merits. Claims 9-11 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for a composition comprising 100% of *L. acidophilus* or for "nutritional or dietary supplement" comprising a sealed, airtight container, such as a capsule.

Therefore, this material raises the issue of new matter and should be deleted.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague, indefinite and confusing in that the composition as claimed is not possible when *L. acidophilus* constitutes 100% thereof.

Claim 12 is confusing in that it is unclear whether the sealed, airtight container is part of the "nutritional or dietary supplement".

Claim 12 is confusing in the recitation of "fixed and maintained for long-term storage". It is unclear how the material is "fixed" and how it is "maintained". Generally "fixed" in this art pertains to immobilization on a carrier. However, this interpretation is not supported by the instant disclosure.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the ATCC Catalogue.

To the extent that the claims read on a composition containing 100% solid, dried *L. acidophilus*, the claims are anticipated by ATCC Catalogue (See, e.g., page 192), because the reference teaches a solid, dried *L. acidophilus* composition. It is noted that shipment of commercial strains of bacteria is routinely conducted in sealed, air-tight containers, such as vials.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn taken with Gelinas, and Spiller *et al.* and further taken with Jolly, Friend and El-Megeed *et al.* for the reasons as stated in the last Office action and the further reasons below.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments are directed to maintaining an admixture in a sealed, airtight container to preserve beneficial health properties. However, the invention as claimed is not clearly directed to such an admixture, particularly considering that it reads on a freeze dried preparation of a vial containing 100% *L. acidophilus*.

As noted in the last Office action, each of Lynn, Gelinas and Spiller *et al.* teaches a product containing bacteria, yeast and protein that is dried and stable. See, e.g., Lynn, col. 12, lines 14-24 and col. 11, lines 43-50; Gelinas, Example 1, 4 and 5; Spiller, bridging paragraph between col. 11 and 12 and Example 2. That the present composition is fixed and maintained as claimed, is noted. However, the meaning of this phrase is unclear. Moreover, providing a dried composition in a container is not deemed to constitute a patentable distinction, even if the container is sealed to make it airtight.

The stable preparation shown in the specification at page 12, Example 1, contains a large amount of soy protein, and the amount of yeast is greater than the amount of *L. acidophilus*. There is no clear correlation between the invention as claimed and this preparation touted as having advantageous properties regarding storage stability of bacteria. Moreover, it is not clear that this material is in dry, granular form. The effects of varying the proportions of ingredients in the manner claimed cannot be readily ascertained. Moreover, there is no claim designated

requirement that the *L. acidophilus* are viable; the only requirement is that the yeast be non-living. From the specification, it is apparent that this is an important feature for the effectiveness of the preparation.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate

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fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Irene Marx

Irene Marx
Primary Examiner
Art Unit 1651